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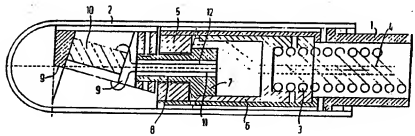

(57) Abstract

An intra-arterial device comprising a catheter having at an end to be inserted into an artery a tip or part (7-10) which is movable relative to the rest of the catheter, and comprising means (3) for causing said part or tip to rotate at a desired speed relative to the catheter and relative to operating means and control apparatus at or near the control end of the catheter, an optical fibre (4) being provided in or connected with the catheter, which fibre extends up to the vicinity of said rotatable tip or part, and adjacent to or in the tip or part marking means (5) being provided, which can be observed through the optical fibre at the control end of the catheter, either the fibre (4) or the marking means (5) being arranged to move along with the rotatable tip or part.

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Title: An intra-arterial device

The invention relates to an intra-arterial device for the examination or treatment of blood vessels, comprising a catheter having at an end to be inserted into an artery a tip which is movable relative to the rest of the catheter, and further comprising means for causing said tip to rotate at a desired speed relative to the catheter and relative to operating means and control appartus at or near the control end of the catheter.

Such a device is known from Dutch patent application No. 8700632. In the known device the fixed part of the catheter adjacent to the rotatable tip is provided with a transducer and the tip is provided with a mirror in slanting position relative to the transducer (Fig.3). Through the rotation of the tip with the mirror high-frequency ultrasonorous vibrations emitted by the transducer are emitted in various directions along a rotating path and the echoes are received in a similar way, so that a picture of a section of the area around the catheter tip can be formed.

Obviously it is possible to provide the rotating catheter tip with the transducer, in which case a mirror is not required. The above publication already shows a rotating transducer, although it is positioned just behind the otherwise stationary tip of the catheter (Fig. 2).

The tip is usually rotated by means of a drive motor positioned at the control end of the catheter, which motor is connected to the tip through a flexible shaft extending

through the catheter. The shaft must be flexible because the catheter, when in operation, is inserted into the artery system of a patient to be examined and must be able to follow all the bends and curves of that system. A problem arises here in that the exact position of the catheter tip is no longer known. Even with a flexible shaft which has been designed with as much stiffness in torsion as possible, the possibility exists that some torsion occurs along the entire length of the shaft, so that the position of the shaft at the motor end does not provide accurate information on the position of the tip at the other end of the shaft.

Furthermore, disturbances in the rotation behaviour of the tip may occur as a result of, for example, friction occurring in the catheter tube or the tip bearing. The result of all this is that in processing the echo signals from the tip of the vibrations emitted by the transducer, which processing is usually done by computer, a signal cannot be attributed accurately to a particular location, so that an inaccurate or even distorted picture is formed of the area around the tip. In fact, the effect of the above phenomena on a display picture will be that within a circle of 360° the sound bundles travel "too fast" around the circumference in one sector and too slowly" somewhat further on. This will certainly give a distorted picture, which can be problematic, especially for certain uses of the device, such as its use in removing obstructions in the artery by means of spark erosion. In that application it is of major importance that the spark

erosion is performed at the position of the obstruction. For this purpose this position should be known exactly. Furthermore, a distorted picture is problematic for a correct diagnostic interpretation of the pictures.

The invention aims to provide a device in which the above problem of the accurate location is solved. This aim is achieved with a device in which an optical fibre is incorporated into or connected with the catheter, which fibre extends up to the vicinity of the rotatable tip or rotatable part, and adjacent to or in that tip or part marking means are provided, which can be observed through the optical fibre at the control end of the catheter, either the fibre or the marking means being arranged to move along with the rotatable tip or rotatable part. In this way, according to the invention, the exact position, or at least the angular position of the rotating part relative to the non-rotating part of the catheter end can be determined at any moment. If, in computer processing of the echo signals of the transducer, the information concerned is also fed to the computer, the computer can always picture each signal in the correct place, so that always a true image is formed.

In a suitable embodiment of the device according to the invention the optical fibre is incorporated in the means for causing the tip of the catheter to rotate, so that the end of the fibre adjacent to the tip rotates along with the tip, the marking means being fixed on, or forming part of, a fixed section of the catheter adjacent to the tip.

Regardless of whether the fibre rotates and the marking means are stationary, or whether the fibre is stationary and the marking means are connected to the rotating tip, according to the invention the marking means are preferably formed by a substantially disc-shaped or ring-shaped body with a surface which is virtually perpendicular to the shaft of the catheter at that point, opposite which surface is the end of the fibre, in which the body rotates when the fibre is stationary and the other way round, so that when the tip rotates the fibre end describes a circular movement along the surface and in which markings have been applied to the surface in the path described thereon by the fibre tip. Suitably, in that embodiment the markings consist of a number of circularly arranged reflecting segments positioned at regular intervals. For a correct location it is desirable that in a suitable place in the series of regularly arranged segments an irregularity is provided. Such an irregularity may consist of the absence of a segment in the suitable place. This absent segment then serves as a point of reference in the circular path. Of course it is also possible that the irregularity consists of a different shape of the segment at that point, compared to the shape of the other segments.

It has to be noted that a device for examination of cavities by means of ultrasound, comprising an optical fibre in combination with marking means, is known per se from French Patent Application No. 2,467,583. Said known device, however, is of the endoscope type, to be used for examination of

intestines and like larger cavities. Therefore it is rather heavy and cannot be used as an intra-arterial device.

The invention will now be described with reference to the drawings, in which:

Fig. 1 is a cross-sectional view of the end of the catheter with a rotatable tip in one embodiment of the device according to the invention; and

Fig. 2 is an illustration of a suitable system of markings for use in the device according to Fig. 1.

Fig. 1 schematically shows a cross-section of the end of the catheter in an embodiment of the device according to the invention. Catheter tube 1 is sealed at that end with an end cap 2 made of a suitable material. The material of end cap 2 should be permeable to the ultrasonorous radiation from the transducer at the end of the catheter, and obviously also to the echoes to be received by the transducer. Extending through catheter tube 1 is a flexible, rotatable shaft 3, which is or can be connected at the other end of the catheter (not shown) to a drive motor to cause shaft 3 to rotate in catheter tube 1. Extending in the centre of shaft 3, whose structure, for that matter, is irrelevant to the present invention, is an optical fibre 4. In the flexible, rotatable shaft 3 are also incorporated suitable electrical wires to feed the transducer in the catheter tip and to carry the signals back from the transducer to the processing means at the other end of the catheter.

Adjacent to the end of catheter tube 1 a disc 5 is installed in it, which is directed perpendicularly to the shaft of tube 1. Disc 5 is fixed to catheter tube 1. The rotatable shaft 3 terminates a certain distance short of disc 5. Secured to the end of shaft 3 is a flange which is connected to a bushing 6. Bushing 6 has an outside diameter slightly smaller than the inside diamter of catheter tube 1, so that bushing 6 can rotate smoothly within tube 1. In the front end of bushing 6 is fixed a cylindrical body 7 with a reduced section 8, which body 7,8 is provided with a central throughbore. The reduced section 8 of cylinder 7, extends through a central opening in the fixed disc 5. The dimensions of the several parts are, for instance, such that section 8 of cylinder 7 is journalled, as it were, in the opening in disc 5.

Secured to the reduced section 8 of cylinder 7, beyond the opening in disc 5, is a holder 9 for transducer 10. Electrical wires and signal wires 11 and 12 leading to the front electrode surface and the back electrode surface, respectively, of the ceramic transducer plate of transducer 10 extend through the throughbore in body 7 and the clearance in bushing 6 to the front end of the rotatable shaft 3, through which shaft 3 they are passed further through the catheter.

At the front end of the rotatable shaft 3 the optical fibre 4 is passed laterally away from the centre of the shaft and deflects to terminate, through a suitable throughbore through a section of cylinder 7 which is adjacent to the outer

circumference of cylinder 7, on the outside of the reduced part 8 just in front of one of the main surfaces of disc 5. When in operation, the catheter tip made up of parts 6 to 10 rotates along with the rotatable shaft 3, since those parts are fixedly secured to shaft 3. The end face of the laterally deflected optical fibre 4 thus describes a circular path along the opposed surface of fixed disc 5. In this path suitable markings are provided on the surface of disc 5. These markings can be detected through the optical fibre. Since the optical fibre is fixedly secured to the rotary tip at the catheter end, in this way the position of the catheter tip can be connected unambiguously to the position of the fixed catheter tube 1. In this way the position of the transducer relative to the fixed catheter tube end is always known. The markings on the fixed disc 5 can, for instance, be detected by shining light on them through the optical fibre 4 and passing the reflected light through the fibre to the other end of the catheter, where suitable processing means can be provided. If the processing means comprise a computer, the marking signals can be connected therein, by means of software which can simply be designed by one skilled in the art, to the echo signals from the transducer. In this way a true image of the surroundings of the catheter tip can be formed which is not distorted by unobserved torsional or frictional decelerations and/or accelerations of the catheter tip.

Fig. 2 shows a top plan view of the fixed disc 5 at the end of the catheter tube 1, viewed from the side where the

front face of the optical fibre 4 is located. On disc 5 a system of markings 13 is provided, which are arranged in a circular path. The system of markings comprises, for instance, a series of reflecting segments 13 which are arranged at regular intervals from each other in a circle. The area between each pair of successive segments is not reflecting. If light is directed to the circular path through the optical fibre 4 moving along the circle of segments 13, consecutive reflection signals will be received through the fibre. At one point in the circular path a segment has been left out. This lacking segment 14 causes an interruption in the regular series of reflection signals and can therefore serve as a point of reference. In this way the location of the end of the optical fibre and hence the position of the rotary tip of the catheter relative to the fixed disc and thus the fixed catheter tube can be determined at any time.

The reflecting segments 13 can be made in any way desired. When the fixed disc is made of glass the ring of segments can be formed by optically etching a chromium layer formed on the glass disc, according to the desired pattern. It is also possible to fix optically reflecting nickle segments on a layer of polyimide on disc 5 or on a disc 5 made of polyimide.

It will be clear that it does not make any difference for a correct location whether disc 5 is fixed relative to the catheter tube and the optical fibre rotates along with the tip, or whether the fibre is fixedly arranged in the catheter

tube and the markings rotate along with the tip. The construction described above, however, is preferred for its compact structure.

To give an impression of the dimensions of the device according to the invention it can be observed that in an embodiment realised in practice disc 5 had a diameter of 1.255 mm, with a central opening of 0.5 mm. Segments 13 each had a height of 0.1 mm, and the number of segments in a circular path on the disc was 99. The rotary tip of the catheter was surrounded by an end cap 2 with a length of 6 mm and a diameter of 1.67 mm, and the catheter tube had a diameter of 1.3 mm.

It will further be clear that other embodiments are possible within the scope of the invention. It is, for example, possible to realise the marking by using a cylindrical body adjacent to the end of the catheter, which body rotates along with the rotary part, and is provided with suitable code segments on its inside surface. In that case the markings extend virtually parallel to the longitudinal axis of the catheter, and the optical fibre should then be positioned in such a way that the end for observing the markings is directed radially, unless a suitable mirror or prism is positioned between the fibre end and the markings.

CLAIMS

1. An intra-arterial device for the examination or treatment of, for example, blood vessels, comprising a catheter having at an end to be inserted into an artery a tip or part which is movable relative to the rest of the catheter, and further comprising means for causing said part or tip to rotate at a desired speed relative to the catheter and relative to operating means and control apparatus at or near the control end of the catheter, characterized in that an optical fibre is provided in or connected with the catheter, which fibre extends up to the vicinity of said rotatable tip or part, and adjacent to or in the tip or part marking means are provided, which can be observed through the optical fibre at the control end of the catheter, either the fibre or the marking means being arranged to move along with the rotatable tip or part.

2. An intra-arterial device according to claim 1, characterized in that the optical fibre is incorporated in the means for causing the tip to rotate, so that the end of the fibre adjacent to the tip rotates along with the tip, the marking means being fixed on, or forming part of, a fixed section of the catheter adjacent to the tip.

3. An intra-arterial device according to claims 1 or 2, characterized in that the marking means are formed by a substantially disc-shaped or ring-shaped body with a surface which is virtually perpendicular to the shaft of the catheter at that point, the end of the fibre being positioned opposite said surface, in which the body rotates when the fibre is stationary and the other way round, so that when the tip rotates the fibre end describes a circular movement along the surface, and in which markings have been applied to the surface in the path described thereon by the fibre tip.

4. An intra-arterial device according to claim 3, characterized in that the markings consist of a number of

circularly arranged reflecting segments positioned at regular intervals.

5. An intra-arterial device according to claim 4, characterized in that in a suitable place in the series of regularly arranged segments an irregularity is provided.

6. An intra-arterial device according to claim 5, characterized in that the irregularity consists of the absence of a segment in the suitable place.

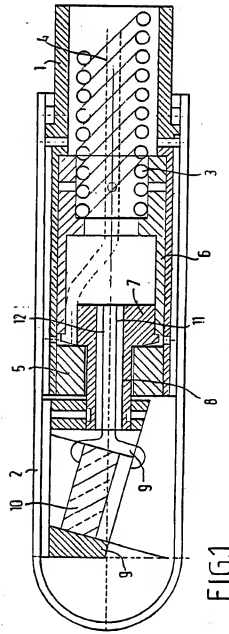

FIG.1

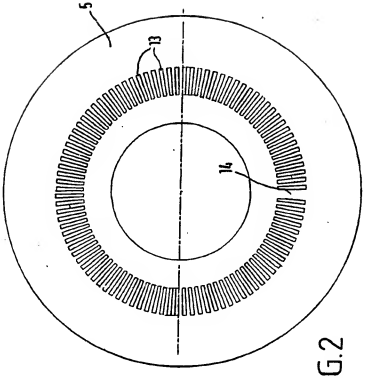

FIG.2

INTERNATIONAL SEARCH REPORT

International Application No PCT/NL 90/00057

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)[6]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl. 5 A61B1/00 ; A61B8/12 ; G10K11/00 ; G01D5/34

II. FIELDS SEARCHED

Minimum Documentation Searched[7]

Classification System	Classification Symbols
Int.Cl. 5	A61B ; G10K ; G01D

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched[8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT[9]

Category *	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No.[13]
X	FR,A,2467583 (OLYMPUS OPTICAL CO. LTD.) 30 April 1981 see page 7, line 22 - page 9, line 4 see page 21, lines 10 - 29 see page 24, lines 10 - 23; figures 1-5, 11, 13	1
A	(cited in the application)	2-6
X	GB,A,2082769 (OLYMPUS OPTICAL CO. LTD.) 10 March 1982 see page 4, lines 32 - 84 see page 5, line 115 - page 6, line 44; figures 1, 2, 9, 10	1
A		2-5
A	DE,A,2948182 (HEWLETT-PACKARD CO.) 10 July 1980 see page 9, lines 1 - 14; figures 1, 4, 5	1, 6

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IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
07 AUGUST 1990	12.09.90
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	HUNT B.W.

Form PCT/ISA/210 (second sheet) (January 1985)

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III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category *	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.
A	NL,A,8700632 (STICHTING BIOMEDICAL ENGINEERING) 17 October 1988 see claims 1-9; figures 1-3 (cited in the application)	1

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ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO.

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SA 36743

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
FR-A-2467583	30-04-81	JP-A- 57052444	27-03-82
		JP-A,B,C56060546	25-05-81
		JP-A,B,C56060547	25-05-81
		DE-A,C 3039523	07-05-81
		GB-A,B 2063474	03-06-81
		US-A- 4391282	05-07-83
GB-A-2082769	10-03-82	None	
DE-A-2948182	10-07-80	US-A- 4266125	05-05-81
		JP-A- 55085218	27-06-80
NL-A-8700632	17-10-88	None	

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